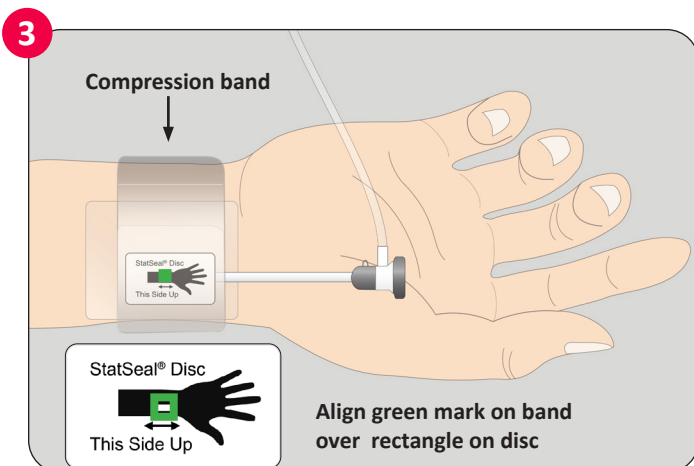
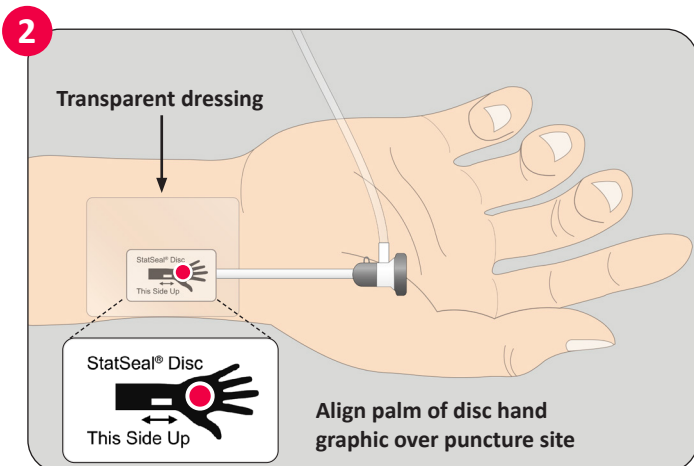
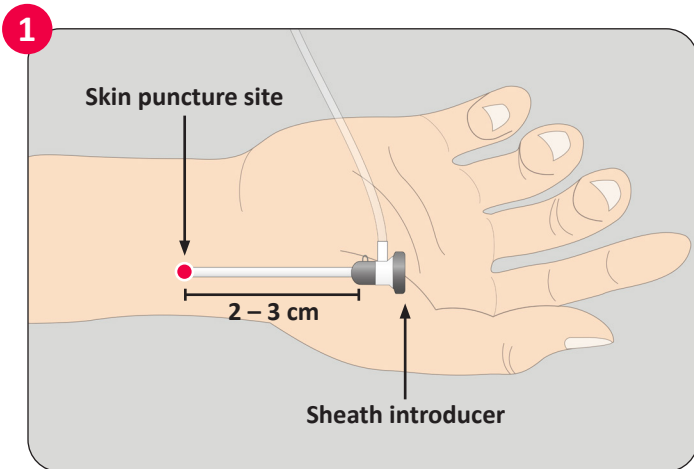


RADIAL HEMOSTASIS PROTOCOL¹⁻⁴

Suggested for Use with StatSeal® Advanced RAD Disc and TR™ Band*

In Procedure Room



StatSeal Advanced RAD Disc placement:

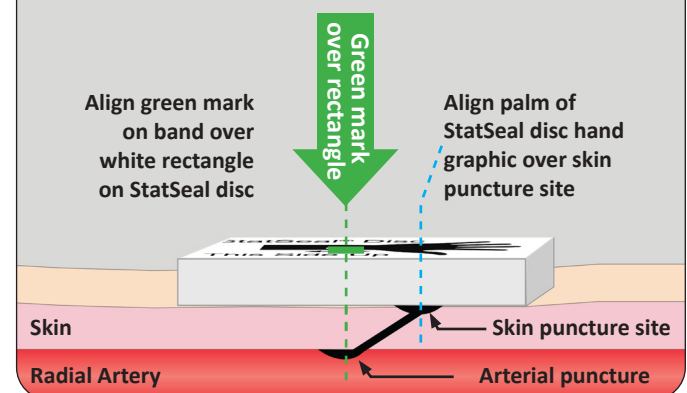
1. Prepare site by cleaning and drying wrist area. Pull sheath back 2-3 cm and aspirate sheath to fill with blood.
2. Remove backing from disc to expose adhesive. Align the palm of the StatSeal disc hand graphic over skin puncture site and place disc with the brown side facing down. Secure disc with transparent dressing.
3. Align green mark on compression band over white rectangle on disc hand graphic and secure compression band firmly around wrist.

Band inflation and timer start:

4. Inflate compression band with 8 cc of air. Remove sheath towards the end of inflation and start timer.

See other side for band deflation in Recovery Area

Side View of StatSeal Advanced RAD Disc Placement



In Recovery Area

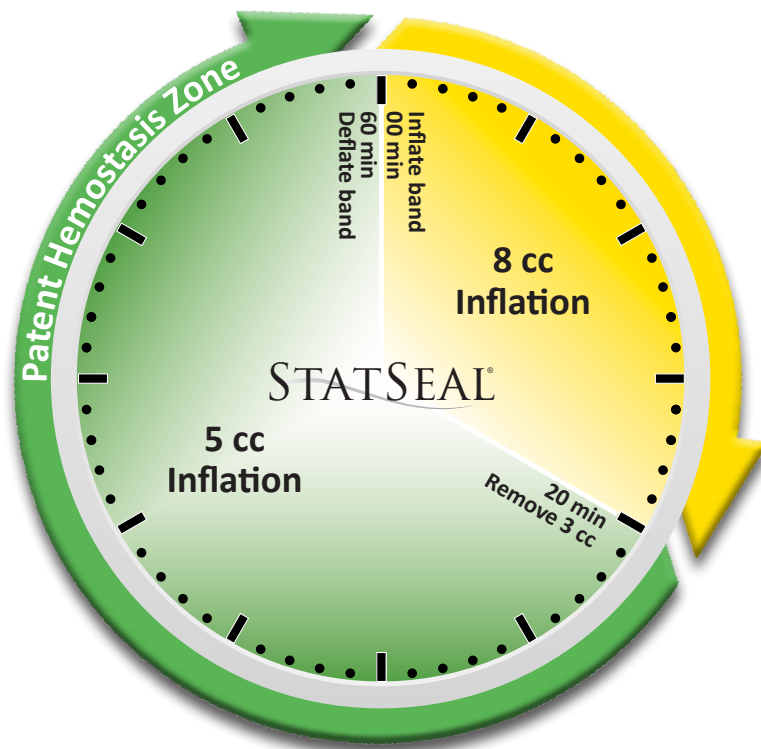
Compression band deflation:

- After 20 minutes, remove 3 cc of air from compression band to bring total volume to 5 cc.
- After a minimum of 60 minutes, fully deflate compression band and leave in place for at least 30 minutes to help immobilize wrist until patient is discharged.

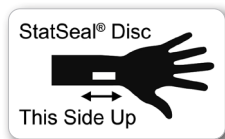
At discharge from recovery area:

- Instruct patient to keep wrist immobile for at least 6 hours, if possible, and to leave disc dressing in place for 24 hours.

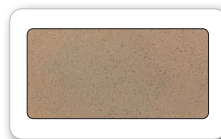
NOTE: If swelling or bleeding develop at any time, inflate balloon with the amount of air last removed. Leave in place for at least 20 minutes and then resume deflation protocol. Protocol is not designed for use with continuous, post-procedural anticoagulation infusions or with any antiplatelet infusions including glycoprotein IIb/IIIa inhibitors.



See other side for disc placement in Procedure Room



Disc top with hand graphic



Disc underside faces skin



Consult Instructions for Use for complete Warnings and Cautions.



*Suggested protocols are based on a compilation of best practices. Protocols should be consistent with the needs of the provider(s) and patient. Air volume and compression time may differ according to the patient condition. Check hemostasis progress and adjust pressure as clinically necessary.

References: [1] Safirstein JG, Tehrani DM, Schussler JM, et al. Radial Hemostasis Is Facilitated With a Potassium Ferrate Hemostatic Patch: The STAT2 Trial. JACC Cardiovasc Interv. 2022 Apr 25;15(8):810-819. [2] Khuddus M, Massaro J, Klass D, et al. TCT-792 Meta-Analysis of Radial Hemostasis Trials Using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc. J Am Coll Cardiol. 2019 Oct, 74 (13 Supplement) B776. [3] Seto AH, Rollefson W, Patel MP, et al. Radial haemostasis is facilitated with a potassium ferrate haemostatic patch: the Statseal with TR Band assessment trial (STAT). EuroIntervention. 2018 Dec 7;14(11):e1236-e1242. [4] Pitta, Sridevi R. et al. Accessing the Wrist: From Data to Tips and Tricks. Interv. Cardiol. Clin. 2020 Jan; 9(1):1-19.